IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Before the Board of Patent Appeals and Interferences

In re the Application of

Inventor : Olivier Gerard et al.

Application No. : 10/596,434

Filed : June 13, 2006

For : SYSTEM FOR GUIDING A MEDICAL INSTRUMENT IN A PATIENT BODY

APPEAL BRIEF

On Appeal from Group Art Unit 3777
Examiner Vani Gupta

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December 15, 2011

I. REAL PARTY IN INTEREST

The real party in interest is Koninklijke Philips Electronics N.V., Eindhoven, The Netherlands by virtue of an assignment recorded June 13, 2006 at reel 017773, frame 0794.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III. STATUS OF CLAIMS

This application was originally filed with Claims 1-14. Claims 1-14 stand finally rejected by the Office action of August 15, 2011 and are the subject of this appeal.

IV. STATUS OF AMENDMENTS

No amendments or other filings were submitted in response to the final rejection mailed August 15, 2011. A notice of appeal was timely filed on November 1, 2011.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

The present invention is a medical system which utilizes an x-ray system to acquire a two-dimensional (2D) x-ray image of a body with a medical instrument in the body. An ultrasound system has an ultrasound probe which acquires three-dimensional (3D) ultrasound data of the medical instrument. A localizer provides localization of the location of the ultrasound probe within the referential coordinate space of the x-ray system. A selector selects a region of interest around the medical instrument in the 3D ultrasound data set to define a first localization of the region of interest within the referential of the ultrasound system. A converter converts the first localization of the ultrasound system into a second localization of the region within the referential of the x-ray system, using the localization of the ultrasound probe. With this registration of the localizations of the two systems, a bi-modal representation of the medical instrument is displayed in which the 2D x-ray image and the 3D ultrasound data of the region of interest are combined using the second localization to provide a bi-modal image which retains the advantages of both imaging modalities.

Claims 1 and 7 are supported by the drawings and specification as seen by reference numerals (#) of the drawings and the specification text

by page and paragraph number (pg., para) of the filed application as follows:

1. A medical system comprising:

a medical instrument {#4; pg. 7, ln. 5-7} to be guided in a patient body,

an X-Ray acquisition system {#5,#6,#7; pg. 7, ln. 7-12} which acquires a two-dimensional X-ray image of said medical instrument,

an ultrasound acquisition system {#8,#9; pg. 7, ln. 13-18} for acquiring a three-dimensional ultrasound data set of said medical instrument using an ultrasound probe,

a localizer {#11; pg. 7, ln. 25-26} which provides a localization of said ultrasound probe within a referential of said X-ray acquisition system,

a selector {#12; pg. 7, ln. 26-29} operable to select a region of interest around said medical instrument in the three-dimensional ultrasound data set, that defines a first localization of said region of interest within a referential of said ultrasound acquisition system,

a convertor {#13; pg. 7, ln. 29-31} which converts said first localization of said region of interest within said referential of the ultrasound acquisition system into a second localization of said region of interest within said referential of the X-ray acquisition system, using said localization of the ultrasound probe,

a generation and display screen {#15; pg. 7, ln. 31-34} which displays a bi-modal representation of said medical instrument in which said two-dimensional X-ray image and the three-dimensional ultrasound data included in said region of interest are combined using said second localization.

14. A method of guiding a medical instrument in a patient body, comprising the steps of:

acquiring a two-dimensional X-ray image of said medical instrument using an X-ray acquisition system, {#60; pg. 14, ln. 19-20}

acquiring a three-dimensional ultrasound data set of said medical instrument using said ultrasound probe and an ultrasound acquisition system, {#61; pg. 14, ln. 21-22}

localizing said ultrasound probe in a referential of said X-ray acquisition system, {#62; pg. 14, ln. 23}

selecting a region of interest of said medical instrument within said 3D ultrasound data set, that define a first localization of said region of interest within a referential of said ultrasound acquisition system, {#63; pg. 14, ln. 24-26}

converting said first localization within said referential of said ultrasound acquisition system into a second X-Ray localization within said referential of the X-ray acquisition system, {#64; pg. 14, ln. 27-28}

generating and displaying a bimodal representation of said medical instrument in which said two-dimensional X-ray image and the three-dimensional ultrasound data included in said region of interest are combined using said second localization. {#65; pg. 14, ln. 29-31}

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether Claims 1-13 were properly rejected under 35 U.S.C. §103(a) as being unpatentable over US Pat. 6,574,492 (Ben-Hiam et al.) in view of US Pat. 6,233,477 (Chia et al.) in view of US Pat. 5,357,550 (Asahina et al.)

B. Whether Claim 14 was properly rejected under 35 U.S.C. §103(a) as being unpatentable over Ben-Hiam et al. in view of Chia et al.

in view of Asahina et al. in view of US pat. pub. no. US2004/0254454 (Kockro)

VII. ARGUMENT

A. Whether Claims 1-13 were properly rejected under 35 U.S.C. §103(a) as being unpatentable over US Pat. 6,574,492 (Ben-Hiam et al.) in view of US Pat. 6,233,477 (Chia et al.) in view of US Pat. 5,357,550 (Asahina et al.)

Amended Claim 1 describes a medical system comprising a medical instrument to be guided in a patient body, an X-Ray acquisition system which acquires a two-dimensional X-ray image of said medical instrument, an ultrasound acquisition system for acquiring a three-dimensional ultrasound data set of said medical instrument using an ultrasound probe, a localizer which provides a localization of said ultrasound probe within a referential of said X-ray acquisition system, a selector operable to select a region of interest around said medical instrument in the three-dimensional ultrasound data set, that defines a first localization of said region of interest within a referential of said ultrasound acquisition system, a converter which converts said first localization of said region of interest within said referential of the ultrasound acquisition system into a second localization of said region of interest within said referential of the X-ray acquisition system, using said localization of the ultrasound probe, and a generation and display device

which displays a bi-modal representation of said medical instrument in which said two-dimensional X-ray image and the three-dimensional ultrasound data included in said region of interest are combined using said second localization. An implementation of the present invention relates a two dimensional X-ray image to the coordinates of a three dimensional ultrasound image including a medical instrument and produces a bi-modal representation of the 2D X-ray image in the three dimensional ultrasound data with the medical instrument represented in the bi-modal representation.

Ben-Hiam et al. describes a system for measuring physiological signals inside the chambers of the heart with two catheters. One catheter is inserted with its tip at a reference location such as the apex of the heart. The other catheter is then manipulated to make the measurements. Each catheter has three sensors at its tip so that their coordinates can be sensed with a field generator. The position of the working catheter can then be known in relation to the coordinates of the reference catheter. At the very end of the description Ben-Hiam et al. say that the positions of the catheters in relation to the heart can be visualized with X-ray or ultrasound. How this is done is not explained. There is also no use of three dimensional ultrasound by Ben-Hiam et al. No bi-modal representations are made by Ben-Hiam et al.

Chia et al. describe a pair of catheters with ultrasound crystals at their tips which serve as beacons. This enables the tip of one catheter to do ranging with the other catheter. No imaging at all is done by Chia et al., only 3D ultrasound locating with the ranging system. No bi-modal representations are made by Chia et al., either.

Asahina et al. are doing x-ray fluoroscopy and ultrasound imaging. Asahina et al. are not using 3D ultrasound, as made clear by their references to "frame memories" for the 2D image frames. Ultrasound images and fluoroscopy images are shown on separate displays, but time-matched so that concurrently acquired fluoroscopy and ultrasound images can be retrieved and shown at the same time. Asahina et al. are not forming bimodal images, either.

It is thus seen that this combination of three patents lacks at least three dimensional ultrasound data sets and bimodal images which combine a 2D X-ray image with a three dimensional ultrasound data set. A selector which selects a location around a medical instrument in 3D ultrasound data is also not found in any of these patents. It is therefore respectfully submitted that the combination of these three patents cannot render Claim 1 or its dependent Claims 2-13 unpatentable.

B. Whether Claim 14 was properly rejected under 35 U.S.C. §103(a) as being unpatentable over Ben-Hiam et al. in view of Chia et al. in view of Asahina et al. in view of US pat. pub. no. US2004/0254454 (Kockro)

Claim 14 was rejected under 35 U.S.C. Sec. 103(a) as being unpatentable over Ben-Hiam et al. in view of Chia et al. in view of Asahina et al. in view of US Pat. pub. 2004/0254454 (Kockro). Claim 14 describes a method of guiding a medical instrument in a patient body, comprising the steps of acquiring a two-dimensional X-ray image of said medical instrument using an X-ray acquisition system, acquiring a three-dimensional ultrasound data set of said medical instrument using said ultrasound probe and an ultrasound acquisition system, localizing said ultrasound probe in a referential of said X-ray acquisition system, selecting a region of interest of said medical instrument within said 3D ultrasound data set, that define a first localization of said region of interest within a referential of said ultrasound acquisition system, converting said first localization within said referential of said ultrasound acquisition system into a second X-Ray localization within said referential of the X-ray acquisition system, and generating and displaying a bimodal representation of said medical instrument in which said two-dimensional X-ray image and the three-dimensional ultrasound data included in said region of interest are combined using said second

localization. The inventive method produces a bimodal representation of a 2D X-ray image in three dimensional ultrasound data with the medical instrument represented in its proper spatial location in the ultrasound data.

Kockro describes a system which produces a heads-up display in front of a surgeon in which the surgeon can visualize CT or MRI images of a surgical site such as the head. Using a probe 9, the surgeon can manipulate the data in space. Like the other three references, Kockro lacks any use of 3D ultrasound data and does not show or suggest bimodal representations of a 2D X-ray image in a 3D ultrasound dataset. The Examiner says that a "bounding box" constitutes selecting the region of interest of a medical instrument, but a reading of the cited passage says that the bounding box only delineates the surgical site, in this patent, surrounding the head. A surgical instrument could be anywhere in the head and is thus not spatially defined by the box. For all of these reasons it is respectfully submitted that Claim 14 is patentable over these four patents.

VIII. CONCLUSION

Based on the law and the facts, it is respectfully submitted that Claims 1-13 are patentable over the combination of Ben-Hiam et al., Chia et al. and Asahina et al. and that Claim 14 is patentable over the combination of Ben-Hiam et al., Chia et al., Asahina et al. and Kockro. Accordingly, it is respectfully requested that this Honorable Board reverse the grounds of rejection of Claims 1-14 of this application which were stated in the August 15, 2011 Office action being appealed.

Respectfully submitted,

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APPENDIX A: CLAIMS APPENDIX

The following Claims 1-14 are the claims involved in this appeal.

1. (previously presented) A medical system comprising:

a medical instrument to be guided in a patient body,

an X-Ray acquisition system which acquires a two-dimensional X-ray image of said medical instrument,

an ultrasound acquisition system for acquiring a three-dimensional ultrasound data set of said medical instrument using an ultrasound probe,

a localizer which provides a localization of said ultrasound probe within a referential of said X-ray acquisition system,

a selector operable to select a region of interest around said medical instrument in the three-dimensional ultrasound data set, that defines a first localization of said region of interest within a referential of said ultrasound acquisition system,

a convertor which converts said first localization of said region of interest within said referential of the ultrasound acquisition system into a second localization of said region of interest within said referential of the X-ray acquisition system, using said localization of the ultrasound probe,

a generation and display screen which displays a bi-modal representation of said medical instrument in which said two-dimensional X-ray image and the three-dimensional ultrasound data included in said region of interest are combined using said second localization.

2. (previously presented) A system as claimed in claim 1, wherein said selector is operable to select a region of interest intended to define a reference plane in which a part of said medical instrument is included.

3. (original) A system as claimed in claim 2, wherein said region of interest is a 2D ultrasound image obtained by sampling said 3D ultrasound data set over said reference plane.

4. (original) A system as claimed in claim 2, wherein said region of interest is obtained by cropping a 3D ultrasound data subset, which lies behind said reference plane or by cropping a slab which is formed around said reference plane.

5. (previously presented) A system as claimed in claim 4, wherein said generation and display screen is intended to generate a volume rendered view of said region of interest within said 3D ultrasound data set.

6. (previously presented) A system as claimed in claim 1, wherein said localizer is intended to localize an active localizer, which has been arranged on said ultrasound probe.

7. (previously presented) A system as claimed in claim 1, wherein said ultrasound probe is equipped with at least three non aligned and interdependent radio-opaque markers and

said localizer is intended to localize said markers in at least a first 2D X-ray image having a first orientation angle in said referential.

8. (previously presented) A system as claimed in claim 7, wherein said localizer is intended to further localize said markers in a second 2D X-ray image having a second orientation angle in said referential.

9. (previously presented) A system as claimed in claim 1, wherein said selector is operable to detect said medical instrument within said region of interest of the 3D ultrasound data set and

said generation and display screen is intended to give to the points of the detected medical instrument in said bimodal representation the X-ray intensity values of the corresponding points in the 2D X-Ray image.

10. (previously presented) A system as claimed in claim 1, comprising

a segmenter operable to segment a wall tissue region in the 3D ultrasound data set and

said generation and display screen is intended to give to the points belonging to said wall tissue region the ultrasound intensity values of the corresponding points of said region of interest.

11. (previously presented) A system as claimed in claim 1, wherein the X-Ray acquisition system is intended to provide live two-dimensional X-Ray images and the ultrasound acquisition system live three-dimensional ultrasound data sets.

12. (previously presented) A system as claimed in claim 11, comprising a controller for periodically triggering the probe localizer.

13. (previously presented) A system as claimed in claim 11, comprising

a compensator operable to compensate a motion between a current three-dimensional ultrasound data set acquired at a current time and a previous three-dimensional ultrasound data set acquired at a previous time.

14. (original) A method of guiding a medical instrument in a patient body, comprising the steps of:

acquiring a two-dimensional X-ray image of said medical instrument using an X-ray acquisition system,

acquiring a three-dimensional ultrasound data set of said medical instrument using said ultrasound probe and an ultrasound acquisition system,

localizing said ultrasound probe in a referential of said X-ray acquisition system,

selecting a region of interest of said medical instrument within said 3D ultrasound data set, that define a first localization of said region of interest within a referential of said ultrasound acquisition system,

converting said first localization within said referential of said ultrasound acquisition system into a second X-Ray localization within said referential of the X-ray acquisition system,

generating and displaying a bimodal representation of said medical instrument in which said two-dimensional X-ray image and the three-dimensional ultrasound data included in said region of interest are combined using said second localization.

APPENDIX B: EVIDENCE APPENDIX

None. No extrinsic evidence has been submitted in this case.

APPENDIX C: RELATED PROCEEDINGS APPENDIX

None. There are no related proceedings.